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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,185	03/26/2004	Arturo J. Angel	524522000501	8005
25226	7590	06/03/2005	EXAMINER	
MORRISON & FOERSTER LLP 755 PAGE MILL RD PALO ALTO, CA 94304-1018			CHANNAVAJALA, LAKSHMI SARADA	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 06/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/810,185

Applicant(s)

ANGEL ET AL.

Examiner

Lakshmi S. Channavajjala

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/28/04; 8/9/04; 2/22/05</u> | 6) <input type="checkbox"/> Other: ____ |

Art Unit: 1615

DETAILED ACTION

Receipt of IDS dated 5-28-04; 8-9-04 and 2-22-05 is acknowledged.

Claims 1-20 are pending in the instant application.

Claim Rejections - 35 USC § 112

Claim 11 recites the limitation "substance" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Objections

Claim 12 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Instant claim, dependent from claim 10 is redundant and does not recite any additional limitations to claim 10.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Art Unit: 1615

Claims 1-20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of copending Application No. 10/655,911. Although the conflicting claims are not identical, they are not patentably distinct from each other. The copending claims recite a kit comprising a composition, a method of making the composition and a method of treating a victim of a discomfort caused by topical application of capsaicin, all of which recite a composition comprising capsaicin, a carrier and another anesthetizing agent. The composition of the co-pending agent is also used for the same purpose as that of the instant claims, wherein the method of treating discomfort caused by capsaicin (in the copending claims) constitutes a species of the generic capsaicin responsive condition of the instant claims. The copending claims also specifically recite the step of applying a carrier- PEG, a second anesthetic agent as well as a thickening agent. Accordingly, the instant claims are anticipated by the copending claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which

Art Unit: 1615

said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,856,361 to Holt in view of Wholehealthmd (product sheet).

Holt teaches a pain reliever composition and a method comprising capsaicin together with another ingredient to neutralize the discomfort caused by capsaicin application to skin. The discomfort and the pain associated with capsaicin listed by Holt include the claimed neuropathic pain etc. (abstract, paragraph between col. 1-2 and col. 5). The composition of Holt includes the second active agent that reduces the skin irritation caused by capsaicin, so as to form a solution, lotion or a patch (col. 2). Holt further teaches adding carriers and thickening agents in the composition so as to provide the required or desired consistency (col. 3). Among the second active agent, Holt teaches polyethylene glycol (PEG)(col. 5, lines 14-22 and example). While Holt does not specially teach treating first with capsaicin and then washing or neutralizing with a carrier, as claimed, Holt does teach applying two components i.e., first capsaicin and a second anesthetic agent such as polyethylene glycol. Thus, while instant claims recite PEG as a carrier, Holt teaches the same as an anesthetic agent, which provides the same benefit as that intended in the instant invention i.e., the PEG of Holt also reduces the discomfort (pruritis, neuropathic pain etc.) caused by capsaicin. Holt, even though teaches PEG, differs from the instant claims in that the reference does not teach washing capsaicin with a composition containing PEG, to solubilize capsaicin.

Art Unit: 1615

Wholehealthmd describes a capsaicin product by the names Axsain and Zostrix, and teaches that capsaicin is prescribed for topical application to relieve the neurological pain, mild to moderate arthritis etc. The data sheet also describes that the common side effects of capsaicin include burning, stinging sensation and suggests washing hands thoroughly after applying the capsaicin containing cream so as to prevent as well as reduce the burning and stinging sensation caused by capsaicin. Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to dilute the amount of capsaicin applied on the skin of a person in need of capsaicin treatment, by washing it with a composition containing capsaicin solubilizer or another anesthetic agent, because Wholehealthmd suggests diluting the amount of capsaicin on the skin, because capsaicin is known to cause burning and stinging sensation while simultaneously providing relief from itching due to poison ivy, arthritis etc (Holt). Accordingly, a skilled artisan would have been motivated to use an appropriate amount of PEG (of Holt) to effectively dilute (or neutralize) the amount of capsaicin on the skin. Further, absent criticality, choosing an appropriate thickener and pH of the composition so as to formulate the composition in the desired form i.e., a cream or lotion or a gel would have been within the scope of a skilled artisan.

Art Unit: 1615

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM - 6.30 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala
Examiner
Art Unit 1615

May 31, 2005